Agenda: Wednesday June 6, 2001
Peripheral and Central Nervous System Drugs Advisory Committee

Food and Drug Administration
Holiday Inn, Bethesda, Maryland

8:00 Call to Order, Introductions
Claudia Kawas, M.D., Acting Chair, PCNS

Conflict of Interest Statement
Sandra Titus, Ph.D., Executive Secretary, PCNS

Consideration of (NDA) 21-196, Xyrem® (sodium oxybate, Orphan Medical, Inc.), proposed to reduce the incidence of cataplexy and to improve the symptom of daytime sleepiness for persons with narcolepsy. A main focus of the deliberations will be on risk management issues.

8:15 FDA Overview of Issues
Overview of Issues, Russel Katz, M.D., Director, Neuropharmacological Drug Products

8:30 Orphan Medical Presentations
Introduction
Dayton Reardan, Ph.D., Orphan Medical

Medical Need, Efficacy and Safety
Emanuel Mignot, M.D., Stanford University Sleep Clinic

Efficacy
William Houghton, M.D., Orphan Medical

Polysomnographic Effects of Xyrem
Jed Black, M.D., Stanford University Sleep Clinic

Safety and Summary of Risks versus Benefits
Bill Houghton, M.D., Orphan Medical

9:30 FDA Response to the Presentation

Questions from the Committee to Orphan Medical

10:00 Break

10:30 FDA Invited Speakers On Risk Management Issues

Epidemiology of GHB Abuse Issues
Carol Falkowski, Hazelden Foundation, Minnesota

Adverse Medical Effects with GHB
Jo Ellen Dyer, Pharm.D. California Poison Control System -San Francisco, University of California San Francisco

11: 00 Sponsor Presentations on Risk Management and Abuse Liability
Bob Balster, Ph.D., Medical College of Virginia

Risk Management
Patti Engel, RN, BSN, Orphan Medical

11:30 Questions from the Committee to the Invited Speakers, Sponsor and the FDA

12:00 Lunch

1:00 Open Public Hearing

2:00 Continued Committee Discussion and Deliberation

5:00 Adjourn